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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/525,985	09/15/2005	Karl Lintner	SEDERM3.3-011 4999		
530 LERNER DAV	7590 12/28/2006 VID, LITTENBERG,		EXAMINER		
KRUMHOLZ	& MENTLIK		AULAKH, CHARANJIT		
600 SOUTH A WESTFIELD,	VENUE WEST NJ 07090		ART UNIT	PAPER NUMBER	
,			1625		
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SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MO	NTHS	12/28/2006	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

-		Applic	ation No.	Applicant(s)					
Office Action Summary		10/52	5,985	LINTNER, KARL					
		Exami	ner	Art Unit					
	<u>.</u>	1	ijit S. Aulakh	1625					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply									
WHIC - Externafter - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE MAIL asions of time may be available under the provisions of 3 SIX (6) MONTHS from the mailing date of this community period for reply is specified above, the maximum statute re to reply within the set or extended period for reply will, eply received by the Office later than three months after ed patent term adjustment. See 37 CFR 1.704(b).	LING DATE OF 17 CFR 1.136(a). In no cation. ory period will apply ar by statute, cause the	THIS COMMUNIC bevent, however, may a red d will expire SIX (6) MON application to become AB	CATION.  eply be timely filed  THS from the mailing date of this of the company o	•				
Status									
1)⊠	Responsive to communication(s) filed of	on 06 October 2	006.						
, —	This action is <b>FINAL</b> . 2b) This action is non-final.								
3)□	ince this application is in condition for allowance except for formal matters, prosecution as to the merits is								
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.								
Dispositi	on of Claims		`						
4)⊠	4)⊠ Claim(s) <u>22-55</u> is/are pending in the application.								
	4a) Of the above claim(s) is/are withdrawn from consideration.								
5)[	5) Claim(s) is/are allowed.								
6)⊠	5)⊠ Claim(s) <u>22-55</u> is/are rejected.								
7)	Claim(s) is/are objected to.								
8)[	Claim(s) are subject to restriction	n and/or electio	n requirement.						
Applicati	on Papers								
9)	The specification is objected to by the E	xaminer.							
10)	The drawing(s) filed on is/are: a)	☐ accepted or	b) objected to b	by the Examiner.					
	Applicant may not request that any objectio	n to the drawing(	s) be held in abeyan	ce. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).									
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.									
Priority u	nder 35 U.S.C. § 119								
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:									
,-	1. Certified copies of the priority documents have been received.								
	2. Certified copies of the priority documents have been received in Application No								
3. Copies of the certified copies of the priority documents have been received in this National Stage									
application from the International Bureau (PCT Rule 17.2(a)).									
* See the attached detailed Office action for a list of the certified copies not received.									
Attachment	·								
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)									
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date									
3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application  6) Other:									

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#### **DETAILED ACTION**

- 1. According to paper filed on Oct. 6, 2006, the applicants have canceled claims 18-21; amended claims 22-38 and furthermore, have added new claims 39-55.
- 2. Claims 22-55 are now pending in the application.

## Response to Arguments

3. Applicant's arguments filed on Oct. 6, 2006 have been fully considered but they are not persuasive regarding enablement rejection, some indefiniteness rejections and most of the prior art rejections. In regard to enablement rejection for making and using the instant compounds alone or in combination with other active agents, the examiner does not agree with the applicant's arguments that the specification is enabling for making instant compounds of formula I based on synthesis of only one compound in instant example 1. There is no teaching or direction provided regarding synthesis of any other compound besides a single compound. The examiner also does not agree with the applicants arguments that the specification is enabling for using the instant compounds either alone or in combination with hundreds of thousands of other active agents such as antitumor compounds, antibiotics, cytotoxic agents etc. for the intended purpose. As stated clearly in the last office action, the instant specification teaches only preparing a single compound and all the in vitro experimental data shown in the instant specification is using this single compound only. There is no teaching or guidance provided or any experimental data presented to show that the combination of even this single compound with other active agents such as antitumor agents will actually maintain its efficacy in the in vitro experiments mentioned in the instant specification.

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In regard to indefiniteness rejections of instant claims 22, 26, 29-32 and 34-38, the examiner does not agree with the applicants arguments regarding definiteness of the terms --- active substances, inorganic support and plant extract ---. The applicants are suggested to include specific substances, active agents and plant extract which are enabled by the instant specification.

In regard to prior art rejections over Su's reference (U.S.Patent 6,313, 134), Krell's reference (WO 99/16441) and Maasbol's reference (U.S. Patent 4,279, 914), the examiner does not agree with the applicant's arguments that these references do not anticipate the instant pharmaceutical composition claims. The applicants have amended claims to include the word, topical to overcome these references. However, first of all, this term introduces new matter as will be discussed later and furthermore, the amended claims are still directed to a pharmaceutical composition and not method claims and therefore, do anticipate the instant pharmaceutical composition claims.

### Conclusion

- 4. Rejection of claims 22-38 as well as of newly submitted claims 39-55 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.
- 5. Rejection of claims 22, 26, 29-32, 34-38 as well of newly submitted claims 39-55 under 35 U.S.C. 112, second paragraph is maintained for the reasons of record.
- 6. Rejection of claims 22-36 as well as of newly submitted claims 47 and 49-55 under 35 U.S.C. 102(a) over Su's reference is maintained for the reasons of record.
- 7. Rejection of claims 22-36 as well as of newly submitted claims 47, 48 and 50-55 under 35 U.S.C. 102(b) over Krell's reference is maintained for the reasons of record.

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8. Rejection of claims 22, 24-36 and newly submitted claims 47 and 50-55 under 35 U.S.C. 102(b) over Maasbol's reference is maintained for the reasons of record.

# NEW GROUNDS OF REJECTION

## Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 22-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicants have amended claims to insert the term –topical ---. This term introduces new matter since this term is not mentioned or described in the original specification.

## Claim Rejections - 35 USC § 102

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- 11. Claim 55 is rejected under 35 U.S.C. 102(a) as being anticipated by Pauly (EP 1145709).

Pauly discloses natural products for cosmetic compositions. The cosmetic composition comprising Boldine anticipates the instant claim when R1 and R4 represent –OH while R2, R3 and R5 all represent methyl group in the instant compounds of formula I.

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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Charanjit S. Aulakh Primary Examiner Art Unit 1625